UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SUSAN SIMON, Plaintiff, -v- SMITH & NEPHEW, INC., Defendant.	13 Civ. 1909 (PAE) OPINION & ORDER

PAUL A. ENGELMAYER, District Judge:

Plaintiff Susan Simon ("Simon") brings this action sounding in negligence, strict products liability, and breach of implied warranty, against medical device manufacturer Smith & Nephew, Inc. ("Smith & Nephew"). Simon alleges that Smith & Nephew designed, manufactured, and distributed the "R3 Acetabular System" used in her hip replacement surgery, that the device was defective, and that it caused her injury. Smith & Nephew now moves to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Simon's state-law claims are preempted, and to the extent they are not preempted, fail to state a claim upon which relief can be granted. For the reasons that follow, Smith & Nephew's motion to dismiss is granted.

I. Background[1]

A. Facts of this Case

On February 16, 2010, Plaintiff Susan Simon received a total hip replacement of her left hip. Am. Compl. ¶ 1. The physician performing Simon's surgery utilized the Smith & Nephew R3 Acetabular System, including a 50mm outer diameter acetabular shell with three holes, a 38mm inside diameter optional metal liner ("optional metal liner" or "R3 metal liner"), and a 38mm femoral head. *Id*. ¶ 32. An x-ray following surgery showed that the prosthesis was properly implanted. *Id*. ¶ 33.

Following the surgery, as early as March 2011, Simon developed "clicking, locking, and radiating pain down her groin area," and experienced elevated serum chromium and cobalt levels. *Id*. ¶¶ 34, 35. By early 2013, Simon's symptoms had worsened; her doctor concluded that her hip pain and the clicking sensation she was experiencing were the result of corrosion and metal wear of the prosthesis, and recommended that she undergo revision surgery. *Id*. ¶¶ 38–40. On May 29, 2013, Simon underwent revision surgery; the R3 metal liner and femoral head were removed, and were replaced with a Smith & Nephew R3 ultra-high molecular weight polyethylene acetabular liner and oxinium femoral head. *Id*. ¶ 43.

On February 15, 2013, Simon filed suit against Smith & Nephew in the Supreme Court of the State of New York. On March 21, 2013, Smith & Nephew filed a notice of removal to this

[1] The facts that form the basis of this Opinion are drawn from the Amended Complaint, Dkt. 23 ("Am. Compl."), affidavits submitted with the parties' briefs, and documents issued by government agencies, of which judicial notice may be taken. *See Leonard F. v. Israel Discount Bank of N.Y.*, 199 F.3d 99, 107 (2d Cir. 1999) ("In adjudicating a Rule 12(b)(6) motion, a district court must confine its consideration 'to facts stated on the face of the complaint, in documents appended to the complaint or incorporated in the complaint by reference, and to matters of which judicial notice may be taken.'") (quoting *Allen v. WestPoint–Pepperell, Inc.*, 945 F.2d 40, 44 (2d Cir. 1991)). On a motion to dismiss, the Court accepts all factual allegations in the Amended Complaint as true.

Court, and, on April 29, 2013, filed a motion to dismiss the Complaint as inadequately pled. Dkt. 1, 15. On July 9, 2013, Simon filed an Amended Complaint alleging negligence, strict products liability (design defect), and breach of implied warranty, arising out of the implantation, during her 2010 hip replacement surgery, of the Smith & Nephew R3 Acetabular System, including the optional metal liner component and the femoral head component. Dkt. 23. On July 29, 2013, Smith & Nephew filed the present motion to dismiss the Amended Complaint, Dkt. 24, and a supporting memorandum of law, Dkt. 25 ("Def. Br."). On September 4, 2013, Simon filed a memorandum of law in opposition to the motion to dismiss. Dkt. 30 ("Pl. Br."). On September 18, 2013, Smith & Nephew filed a reply. Dkt. 31 ("Def. Reply Br.").

B. Regulatory Framework

The Medical Devices Amendments of 1976 ("MDA"), 21 U.S.C. § 360c, *et seq*., establishes "various levels of oversight for medical devices, depending on the risks they present." *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008). Devices that are primarily used for "supporting or sustaining human life" or that "present[] a potential unreasonable risk of illness or injury" are designated Class III devices. 21 U.S.C. § 360c(a)(1)(C). Class III devices are subjected to the highest level of government oversight, and must receive premarket approval ("PMA") from the Food & Drug Administration ("FDA") before being placed on the market. *See id*. To obtain PMA approval, applicants must submit to the FDA extensive records as to clinical trials, design specifications, manufacturing processes, quality controls, and proposed labeling, and advertising for review. *See id.* § 360e; *see also Riegel*, 552 U.S. at 318. The FDA will grant approval to a device only if it determines, on the basis of these submissions, that there is reasonable assurance of the device's safety and effectiveness. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e. The process is "rigorous" and takes years to complete. *Riegel*, 552 U.S. at 318. Even

following approval, any incidents involving serious injury caused by the device must be reported to the FDA. *See id.* at 319–20. Manufacturers must also obtain supplemental PMA approval for any change to "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). The FDA may withdraw PMA approval at any time. *See id.* at 319–20.

Because the process is so rigorous and time-consuming, most devices are not actually submitted for PMA approval. *See Gelber v. Stryker*, 752 F. Supp. 2d 328, 331 (S.D.N.Y. 2010) ("*Gelber I*") ("Very few devices undergo the much more demanding PMA process—for example, in 2005, only 1% of Class III medical devices were subject to the PMA process."); *see also Riegel*, 552 U.S. at 317. More often, devices come to market through the § 510(k) process, by which the FDA grants approval based on "substantial[] equivalen[ce]" to devices that are already on the market. *See Riegel*, 552 U.S. at 317.

C. History of the Device[2]

On June 6, 2007, Smith & Nephew received § 510(k) approval for the REFLECTION 3 Acetabular System ("R3 Acetabular System"). The R3 Acetabular System as described in the 510(k) summary is a cementless hip replacement prosthesis "consist[ing] of Acetabular shells and liner," specifically "R3 shells . . . manufactured from titanium alloy" and "liners . . . manufactured from cross-linked polyethylene."[3] Cross-linked polyethylene is not a metal, and the 510(k) summary contains no mention of an optional metal liner.

[2] For the purpose of resolving the present motion, the Court takes judicial notice of public records contained on the FDA website. *See Gale v. Smith & Nephew, Inc.*, No. 12 CV 3614 (VB), 2013 WL 563403, at *1 n.2 (S.D.N.Y. Feb. 13, 2013).

[3] FDA 510(k) Summary, number K070756, *available at* http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K070756.

Smith & Nephew later introduced the R3 metal liner that Simon alleges was implanted during her surgery. *See* Am. Compl. ¶ 26. The R3 metal liner was designed for use with the Birmingham Hip Resurfacing ("BHR") System, *id*. ¶¶ 26–29, a separate PMA-approved device[4] described in the FDA approval papers as a "metal on metal resurfacing artificial hip replacement system, surgically implanted to replace a hip joint."[5] Smith & Nephew submitted the R3 metal liner for FDA review, as required by federal regulations; the FDA granted supplemental PMA approval on November 13, 2008,[6] and again on December 31, 2009.[7]

On June 1, 2012, Smith & Nephew released an urgent field safety notice regarding the optional metal liner component and issued a voluntary withdrawal of the device component. Am. Compl. ¶ 44.

II. Applicable Legal Standards

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim will only have "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A complaint is properly

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[4] The BHR System received PMA approval on May 9, 2006. *See* FDA Premarket Approval Summary, PMA number P040033, *available at* http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=17306.

[5] Device Approvals and Clearances: Birmingham Hip Resurfacing (BHR) System - P040033, *available at* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078189.htm (last updated September 5, 2013).

[6] *See* FDA Premarket Approval Summary, PMA number P040033, Supplement number S006, Declaration of Glenn S. Kerner in Support of Motion to Dismiss ("Kerner Decl."), Ex. A.

[7] *See* FDA Premarket Approval Summary, PMA number P040033, Supplement number S013, Kerner Decl., Ex. B.

dismissed, where, as a matter of law, "the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 558.

In considering a motion to dismiss, a district court "must accept as true all well-pleaded factual allegations in the complaint, and 'draw[ ] all inferences in the plaintiff's favor.'" *Allaire Corp. v. Okumus*, 433 F.3d 248, 249–50 (2d Cir. 2006); *see also Famous Horse Inc. v. 5th Ave. Photo Inc.*, 624 F.3d 106, 108 (2d Cir. 2010) ("We review the district court's grant of a Rule 12(b)(6) motion to dismiss *de novo*, accepting all factual claims in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor."). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* "[R]ather, the complaint's *factual* allegations must be enough to raise a right to relief above the speculative level, *i.e.*, enough to make the claim plausible." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (citing *Twombly*, 550 U.S. at 555, 570) (internal quotation marks omitted) (emphasis in *Arista Records*); *accord Goldin v. Smith & Nephew, Inc.*, No. 12 CV 9217 (JPO), 2013 WL 1759575, at *2 (S.D.N.Y. April 24, 2013).

III. Discussion

A. Federal Preemption of State-Law Claims Under the MDA

The MDA expressly preempts any state requirement "which is different from, or in addition to, any requirement applicable . . . to the device [under federal law]," and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device [under federal law]." 21 U.S.C. § 360k(a).

In *Riegel v. Medtronic, Inc.*, the Supreme Court held that PMA approval for a particular device constitutes a requirement applicable to the device under federal law within the meaning of the MDA's express preemption clause. *See* 552 U.S. at 321–23. State common-law tort claims are expressly preempted, the Court explained, to the extent that they (1) relate to the safety and effectiveness of a PMA-approved device; and (2) impose standards "different from, or in addition to" federal requirements. *Id.* at 323–330. However, the *Riegel* Court noted, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330; *see Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 153 (S.D.N.Y. 2011) ("*Gelber II*").

Courts interpreting *Riegel* have held that state-law claims "parallel" federal regulations, and thus are not preempted, only in a narrow set of circumstances: where the defendant allegedly violated FDA regulations, but the violation is not itself the basis of the claim. *See Gale v. Smith & Nephew*, No. 12 CV 3614 (VB), 2013 WL 563403, at *3 (S.D.N.Y. Feb. 13, 2013) (citing cases and noting that "plaintiff must be suing for conduct that *violates* federal law, or Section 360k(a) pre-empts the claim, but the plaintiff must not be suing *because* the conduct violates federal law, because he has no private right to bring such a claim") (internal quotation marks, citation, and alterations omitted) (emphasis in *Gale*). Put more plainly, "'section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law,'" *i.e.* received PMA approval, "'but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law,'" *i.e.*, failure to conform to PMA-approved device specifications, *id.* (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010)) (alteration in *Gale*).

To avoid preemption and satisfy the *Twombly* and *Iqbal* pleading standards, plaintiffs suing with regard to a PMA-approved device cannot simply make the conclusory allegation that defendant's conduct violated FDA regulations. *See id.* at *4; *see also Gelber II*, 788 F. Supp. 2d at 155. "Rather, to state a parallel claim plaintiff must 'set forth facts pointing to specific [premarket approval] requirements that have been violated,' and link those violations to his injuries." *Gale*, 2013 WL 563403, at *4 (quoting *Wolicki–Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)) (alteration in *Gale*); *see also Gelber II*, 788 F. Supp. 2d at 155.

B. Simon's Claims

The Amended Complaint alleges three theories of liability under New York common law: strict liability, negligence, and breach of implied warranty. Each is premised on the theory that Smith & Nephew defectively designed the prosthesis implanted during her hip replacement, and that the defective design of that device caused her injuries. Simon argues that those claims are not preempted by the MDA because they do not relate to the safety and effectiveness *of a PMA-approved device*: The R3 Acetabular system she alleges to have caused her injuries was approved via the § 510(k) process, not the PMA process, and § 510(k) approval does not have the same preemptive force as PMA approval. Pl. Br. 11−14.

Smith & Nephew responds by noting that each of the state-law claims in the Amended Complaint challenges the safety and effectiveness of the optional metal liner; and the R3 metal liner was indeed PMA-approved, albeit in connection with the separate BHR System. Def. Br. 7−11. Further, Smith & Nephew states, Simon's physician independently chose to use the R3 metal liner, which was PMA-approved for use with the BHR System, with another system for which it was not PMA-approved; that choice does not defeat preemption of claims against the

manufacturer. Def. Reply Br. 3−4. Smith & Nephew also argues that, for each cause of action, the Amended Complaint fails to state a claim. Def. Br. 11−18.

Importantly, the parties, although differing as to whether Simon's state common-law claims are preempted, do not dispute that those claims relate to the safety and effectiveness of the Smith & Nephew device implanted during her hip replacement surgery. Nor do they appear to dispute that Simon's claims would impose requirements "different from, or in addition to" federal requirements. The parties' only dispute with respect to preemption, therefore, is whether the claims in the Amended Complaint concern a device that received PMA approval, in which case those claims are preempted. In addition to the preemption analysis, the Court also must address Smith & Nephew's argument, as to each claim, that Simon has otherwise failed to allege facts that state a claim for relief. Because Simon's characterizations of the device that caused her harm subtly differ among her claims, the Court addresses each of Simon's three common-law claims separately, addressing preemption analysis in the course of addressing each claim.

1. Strict Products Liability

To state a claim for strict products liability under a design defect theory, a plaintiff must allege that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001).

In its claim for strict products liability, the Amended Complaint states that "the R3 Acetabular System and relevant components as designed, posed a substantial likelihood of harm, specifically, its propensity to deteriorate prematurely and release cobalt and chromium into the human body" as a result of the "metal on metal components . . . grind[ing] against each other." Am. Compl. ¶ 62. The Amended Complaint makes clear that the focus of the strict liability

design defect claim is its theory of "metal-on-metal" contact, *id.* ¶ 63, *i.e.*, in which the "optional metal liner component" of the R3 Acetabular System, *id.* ¶ 65, grinded against the metallic femoral head component of the same system. To this end, the Amended Complaint alleges, "[i]t was feasible for Smith & Nephew to design the R3 Acetabular System and its relevant components, including the liner component, in a safer manner. Defendant was able to quickly withdraw the optional metal liner component from the R3 Acetabular System and continue to offer nonmetal liner options, such as plastic and ceramic, for the R3 Acetabular System." *Id.* The Amended Complaint goes on to allege that "[a]t all times herein mentioned, the R3Acetabular System, including when utilized with the metal liner, was in a defective condition and unsafe, and defendant knew, or had reason to know, that said product was defective and unsafe, especially when used in the form and manner as designed, manufactured, marketed and distributed by the defendant." *Id.* ¶ 66.

The Amended Complaint's strict liability theory, however, suffers from a fundamental flaw. In making these allegations, the Amended Complaint describes the R3 Acetabular System in a manner flatly inconsistent with that system as defined and approved by the FDA. The FDA approval papers for the R3 Acetabular System nowhere mention an optional metal liner component. And, indeed, the Amended Complaint elsewhere alleges that the optional metal liner was approved by the FDA for use with another Smith & Nephew system altogether: the BHR System, a hip resurfacing system. *See id.* ¶ 26.

Under these circumstances, Simon's claim for strict products liability based on a design defect theory must fail. Simon does not allege that Smith & Nephew took any act to design an R3 Acetabular System to contain an optional metal liner component. Nor does her Amended Complaint allege even that Smith & Nephew encouraged medical personnel to use the optional

metal liner component from the BHR System in conjunction with the R3 Acetabular System. Put differently, the Amended Complaint does not allege any facts that could plausibly indicate that a Smith & Nephew product, *as designed*, was defective and caused her injuries. Instead, the Amended Complaint appears to intimate that the use of the BHR System's optional metal liner component in conjunction with the R3 Acetabular System caused Simon injury. Without concrete allegations tying Smith & Nephew to the decision to make such use of the optional metal liner component, however, this conduct does not state a claim for strict products liability, let alone on a design defect theory.

The Amended Complaint does allege that Smith & Nephew voluntarily recalled the optional metal liner. *See id.* ¶¶ 44, 65. However, that allegation does not support Simon's claim of a design defect with respect to the R3 Acetabular System, which, as noted, did not include such a liner.[8] In any event, "[t]he bare fact of the voluntary recall does not suffice to prove a design defect." *Goldin*, 2013 WL 1759575, at *4. And Simon does not allege any facts indicating that the Smith & Nephew R3 Acetabular System *as designed* was defective or created an unreasonable risk of harm. Merely pleading the legal conclusion is insufficient. *See id.* (allegation that the product posed a "risk of harm because of its propensity to dislocate" fails to "identify any particular problem in the design of the product," and thus fails to support design defect claim).

Independently, the Amended Complaint fails to allege facts that would indicate the existence of a feasible alternative design that could have prevented Simon's injuries. The Amended Complaint states that Smith & Nephew could have designed a hip replacement system that did not create metal-on-metal interactions, and such a design would have been safer. *See*

[8] Even if the Amended Complaint had so alleged, a design defect claim made with respect to the liner itself would be preempted, as discussed in greater length below.

Am. Compl. ¶ 62 ("other hip replacement manufacturers . . . manufactured total hip replacement systems which were not metal-on-metal and that do not deteriorate prematurely and do not release cobalt and chromium into the human body"); *see also id.* ¶¶ 63, 65, 73. But, as explained, the R3 Acetabular System as designed did not create metal-on-metal interactions involving the optional metal liner. In any event, an allegation that Smith & Nephew could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect. *See In re Fosamax Prods. Liab. Litig.*, 924 F. Supp. 2d 477, 485 (S.D.N.Y. 2013) (a claim for design defect requires a "'showing that an alternative design was feasible and safer'") (quoting *Urena v. Biro Manu. Co.*, 114 F.3d 359, 365 (2d Cir. 1997)); *cf. Goldin*, 2013 WL 1759575, at *5 ("the question is whether a safer alternative design for *this* product existed") (emphasis in original).[9]

Pressed at argument about the fact that the R3 Acetabular System does not contain an option metal liner, Simon's counsel changed tack, arguing that the optional metal liner alone, rather than the interaction of the liner with components of the R3 Acetabular System, was the source of Simon's injury. A plaintiff may not, of course, amend her theory of liability by means of statements during argument. *See Chauvet v. Local 1199, Drug, Hosp. & Health Care Empls. Union, et al.*, Nos. 96 CV 2934 (SS), 96 CV 4622 (SS), 1996 WL 665610, at *6 (S.D.N.Y. Nov. 18, 1996). But even if the Amended Complaint were fairly read to assert a claim of design defect based solely on the optional metal liner, any such claim would be preempted. That is

[9] Although the point is arguably implicit, the Amended Complaint also does not concretely claim, as required to state a claim for design defect, that a differently-designed hip replacement device (one without metal-on-metal interactions) could have been used during Simon's surgery and would have prevented her injuries. *See Bertini v. Smith & Nephew, Inc.*, No. 13 CV 0079 (BMC), slip op. (E.D.N.Y. July 15, 2013), Kerner Decl., Ex. D, at 6 (rejecting claim of feasible alternative design because "[t]here is no way to tell whether other R3 liners would have been appropriate for implantation in plaintiff").

because the optional metal liner received supplemental PMA approval in conjunction with the BHR System. As noted, design defect claims regarding a PMA-approved device are squarely preempted by the MDA. *See Riegel*, 552 U.S. at 323, 327−30. Such preemption extends to a component of a PMA-approved device. *See Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010) ("To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers."); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (separating components of PMA-approved device to apply different preemption analysis "makes no sense").

For these reasons, Simon's strict liability claim, based on a claim of a design defect, must be dismissed for failure to state a claim upon which relief can be granted.

2. Negligence

"'New York courts generally consider strict products liability and negligence claims to be functionally synonymous.'" *Goldin*, 2013 WL 1759575, at *6 (quoting *Pinello v. Andreas Stihl Ag & Co. KG*, No. 08 CV 452 (LEK) (RFT), 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011)); *see also Colon*, 199 F. Supp. 2d at 83 ("for the purposes of analyzing a design defect claim, the theories of strict liability and negligence are virtually identical"). "To make out a prima facie case for negligence in New York, a plaintiff must show (1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, *i.e.* reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or damage." *Colon*, 199 F. Supp. at 82.

Simon's negligence claim is flawed for the same reason as her strict products liability claim: Her Amended Complaint does not allege facts that plausibly indicate that a non-PMA approved device was defective and caused her injuries. *See Gelber II*, 788 F. Supp. 2d at 155 ("Under New York law, in order '[t]o plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective . . . and that the defect was the cause of plaintiff's injury.'") (quoting *Colon*, 199 F. Supp. 2d at 85) (first alteration in *Gelber II*). In claiming negligence, Simon alleges that Smith & Nephew "failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the R3 Acetabular System, and its components, *specifically the optional metal liner component* and femoral head component." Am. Compl. ¶ 49 (emphasis added). But, as noted above, the optional metal liner (which was part of the BHR system) received PMA approval, and claims of negligent manufacture with respect to PMA-approved devices are preempted. *See* Part III.B.1, *supra*. Thus, to the extent that Simon means to claim negligence on the ground that the optional metal liner was defective, her negligence claim is preempted.

To the extent the Amended Complaint's negligence claim takes aim at the overall R3 Acetabular System and not just the optional metal liner, which the Amended Complaint wrongly treats as part of that system, it fails to state a claim. The Amended Complaint contains a long list of conclusory allegations as to the ways in which Smith & Nephew was purportedly negligent in designing the R3 Acetabular system. These include: "designing and manufacturing the R3 Acetabular System without thorough and proper testing"; "not conducting sufficient testing programs to determine whether the aforesaid R3 Acetabular System was safe for use"; "negligently failing to adequately and correctly warn . . . of the danger of the R3 Acetabular

System"; "negligently failing to recall its dangerous and defective R3 Acetabular System at the earliest date that it became known to Smith & Nephew that said R3 Acetabular System was, in fact, dangerous and defective"; "failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably foreseeably come into contact with and use the R3 Acetabular System"; "negligently advertising and recommending the use of the R3 Acetabular System without sufficient knowledge as to its dangerous propensities"; "negligently representing that the R3 Acetabular System was safe for use for its intended purpose"; "negligently representing that the R3 Acetabular System had equivalent safety and efficacy as other, non-defective total hip replacement systems"; "negligently designing the R3 Acetabular System in a manner which was dangerous to its recipients." Am. Compl. ¶ 50. But the Amended Complaint does not contain any concrete factual allegations to back up these legal conclusions. In short, there are not specific allegations plausibly indicating that the R3 Acetabular System was defective or that Smith & Nephew breached a duty of care; the Amended Complaint instead is limited to rote incantations of the elements of negligent manufacture.

For these reasons, the Amended Complaint fails to state a claim for negligence. *See Bertini*, Kerner Decl., Ex. D, at 9 (dismissing similar allegations as "boilerplate" because "[p]laintiffs fail to support them with any facts"); *see also Goldin*, 2013 WL 1759575, at *6 (dismissing negligence claim premised on the allegation that Smith & Nephew "knew or should have known about the risks associated with the R3 Constrained Acetabular Liner" because the plaintiff did "not offer factual allegations to support this legal conclusion").

3. Breach of Implied Warranty

Under New York law, "[a] breach of implied warranty claim requires proof of the following three elements: (1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Plemmons v. Steelcase Inc.*, No. 04 CV 4023 (LAP), 2007 WL 950137, at *3 (S.D.N.Y. Mar. 29, 2007) (internal quotation marks and citation omitted).

For much the same reasons as reviewed above, the Amended Complaint fails to allege that a non-PMA approved device was defectively designed. It thus fails to state a claim for breach of implied warranty. *See Lewis v. Abbott Labs.*, No. 08 CV 7480 (SCR) (GAY), 2009 WL 2231701, at *6 (S.D.N.Y. July 24, 2009) (holding that where "plaintiff has not pleaded necessary elements to support a design . . . defect claim," "plaintiff has failed to plead an essential element of her breach of implied warranty claim"). The Amended Complaint alleges generically that Smith & Nephew "impliedly represented and warranted . . . that the R3 Acetabular System was safe and of merchantable quality," Am. Compl. ¶ 82, and that these "representations and warranties were false, misleading, and inaccurate in that the R3 Acetabular System, including the optional metal liner, was unsafe, unreasonably dangerous, and improper, not of merchantable quality and otherwise defective," *id.* ¶ 83. This barebones allegation, however, is conclusory. There are no concrete factual allegations to support the claim that the R3 Acetabular System was defective as designed. To the extent that the Amended Complaint implies that the inclusion of an optional metal liner in that system rendered it defective, that claim is defeated by the fact that the R3 Acetabular System, as reviewed and approved by the FDA, did not contain any such liner. And, to the extent that the Amended Complaint may be

read to allege that the optional metal liner itself was defective and Smith & Nephew breached an implied warranty with respect to that liner, that claim is preempted, for the reasons reviewed above. Simon's breach of implied warranty claim must be dismissed.

In sum, the three claims in the Amended Complaint, all of which are premised on theories of a design defect, fail to state a claim against Smith & Nephew upon which relief can be granted. To the extent Simon's theory is that the interplay between an optional metal liner from the BHR system caused harm to her when used in tandem with the separate R3 Acetabular System, Simon may wish to explore whether any timely claim for relief can be made against the person or entities responsible for the decision, in connection with her hip procedure, to use the metal liner from the BHR system in connection with the R3 Acetabular System.

CONCLUSION

For the foregoing reasons, Smith & Nephew's motion to dismiss is granted. The Clerk of Court is directed to terminate the motions at docket numbers 15 and 24, and to close this case.

SO ORDERED.

Paul A. Engelmayer

Paul A. Engelmayer
United States District Judge

Dated: December 3, 2013
New York, New York